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Display Date 8-27-04
Publication Date 8-30-04
Certifier A. Corbin

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

# Oral Dosage Form New Animal Drugs; Spectinomycin Dihydrochloride Oral Solution

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for the oral use of spectinomycin dihydrochloride pentahydrate oral solution in pigs under 4 weeks of age for the treatment and control of infectious bacterial enteritis.

**DATES:** This rule is effective [*insert date of publication in the* **Federal Register**].

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov.*

**SUPPLEMENTARY INFORMATION:** Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–364 that provides for oral use of SPECMED (spectinomycin dihydrochloride pentahydrate) Scour-Chek in pigs under 4 weeks of age for the treatment and control of infectious bacterial enteritis (white scours) associated with *Escherichia coli.* Cross Vetpharm Group Ltd.'s SPECMED Scour-Chek is approved as a generic copy of Phoenix Scientific, Inc.'s SPECTAM Scour Halt, approved under NADA 033–157. The



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ANADA is approved as of July 29, 2004, and the regulations are amended by removing 21 CFR 520.2122 and by adding 21 CFR 520.2123c to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

**List of Subject in 21 CFR Part 520**

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 520.2122 [Removed]**

■ 2. Section 520.2122 is removed.

■ 3. Section 520.2123c is added to read as follows:

**§ 520.2123c Spectinomycin dihydrochloride pentahydrate solution.**

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) spectinomycin activity.

(b) *Sponsors.* See Nos. 000856, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount.* Administer 5 mg per pound (lb) of body weight orally twice daily for 3 to 5 days.

(2) *Indications for use.* For the treatment and control of infectious bacterial enteritis (white scours) associated with *E. coli* in pigs under 4 weeks of age.

(3) *Limitations.* Do not administer to pigs over 15 lb of body weight or over 4 weeks of age. Do not administer within 21 days of slaughter.

Dated: 8/17/04

August 17, 2004.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

**BILLING CODE 4160–01–S**